

<b>PTO-1390</b> <b>TRANSMITTAL LETTER TO THE UNITED STATES</b> <b>DESIGNATED/ELECTED OFFICE (DO/EO/US)</b> <b>CONCERNING A FILING UNDER 35 U.S.C. 371</b>		<b>ATTORNEY DOCKET NUMBER</b> <b>7388/84495</b>
		<b>10/15/2005</b> <small>U.S. APPLICATION NUMBER KNOWN AS: 11/157,611 US Appln No.: Not Yet Assigned</small>
INTERNATIONAL APPLN. NO.: PCT/JP2004/007403	INTERNATIONAL FILING DATE International Filing Date: 24 May 2004	PRIORITY DATE CLAIMED 23 May 2003
<b>TITLE OF INVENTION</b> <b>TRANSDERMAL FORMULATION FOR EXTERNAL APPLICATION CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY ANALGESIC, AND INTERLEUKIN-1<math>\alpha</math> PRODUCTION INHIBITOR</b>		
<b>APPLICANT(S) FOR DO/EO/US</b> Atsutoshi IKESUE, Kazuhisa YOSHITAKE, Kenji ATARASHI, Koichi IKESUE, Michinori SAKAI, Amarender REDDY, Yoshiteru MOTOKI, Dange VEERAPANENI		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. Please do not delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p><b>Items 11. to 20. below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> </ol>		

21. The following fees are submitted:

a) Basic national fee \$300.00  
 b) Examination fee \$200.00  
 c) International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400.00

**TOTAL OF ABOVE CALCULATIONS =**

Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	RATE	
34 - 100	0 / 50 =	0	x \$250.00	0.00

Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE	
Total claims	13	- 20	= 0	x \$50.00	0.00
Independent Claims	4	- 3	= 1	x \$200.00	\$ 200.00

**MULTIPLE DEPENDENT CLAIM(S) (if applicable)**

<b>TOTAL OF ABOVE CALCULATIONS =</b>	\$ 1,100.00
Applicant(s) assert entitlement to Small Entity Status (37 CFR 1.27), thus reducing the filing fee by half to:	0.00

**SUBTOTAL =**

Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).	0.00
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<b>TOTAL NATIONAL FEE =</b>	\$ 1,100.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.	0.00

<b>TOTAL FEES ENCLOSED =</b>	\$ 1,100.00
	\$

**AMOUNT TO BE:**

	Charged	\$
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a.  A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.  
 b.  Please charge my Deposit Account No. 06-1135, regarding our Order No. 7388/84495, in the amount of \$ 1,100 to cover the above fees. A duplicate copy of this sheet is enclosed.  
 c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1135 regarding Order No. 7388/84495. A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO: CUSTOMER No. 42798

FITCH, EVEN, TABIN & FLANNERY  
 1801 K Street, NW, Suite 401L  
 Washington, DC 20006-1201  
 Telephone: (202) 419-7000  
 Facsimile: (202) 419-7007

  
 SIGNATURE

NAME: Kendrew H. Colton, Reg. No. 30,368  
 Samuel P. Burkholder, Reg. No. 40,541  
 Date: November 22, 2005

13.  A preliminary amendment TO BE ENTERED BEFORE CALCULATING FEES DUE.

14.  An Application Data Sheet under 37 CFR 1.76.

15.  A substitute specification.

16.  A power of attorney and/or change of address letter.

17.  A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.

18.  A second copy of the published international application under 35 U.S.C. 154(d)(4).

19.  A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

20.  Other items or information:

International Search Report (PCT/ISA/210)

PCT Notification Concerning Submission of Transmittal of Priority Document (PCT/IB/304)

PCT Notice Informing the Applicant of the Communication of the International Application to the Designated Offices (PTO/IB/308)

Copy of Front Page of WO 2004/112837 A1

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO. PCT/JP2004/007403	ATTORNEY DOCKET NUMBER 7388/84495
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Atsutoshi IKESUE et al.

New 371 Patent Application

Filed: Herewith, November 22, 2005

Attorney Docket No.: 7388/84495

Confirmation No.: Not Yet Assigned

Customer No.: 42798

Title: TRANSDERMAL FORMULATION FOR EXTERNAL APPLICATION  
CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY ANALGESIC, AND  
INTERLEUKIN-1 $\alpha$  PRODUCTION INHIBITOR

**GENERAL AUTHORIZATION FOR PETITION FOR  
EXTENSION OF TIME UNDER 37 C.F.R. §1.136(a)(3)**

MAIL STOP PCT  
Commissioner for Patents  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Applicant(s) hereby request under 37 C.F.R. §1.136(a)(3) by this general authorization that any concurrent or future reply submitted by Applicant(s) to the United States Patent and Trademark Office for the above-identified patent application requiring a petition for an extension of time under §1.136(a) for its timely submission be treated as incorporating therein a petition for an extension of time for the appropriate length of time.

If Applicant(s) do not timely pay for any extension fee(s) pursuant to 37 C.F.R. §1.136(a) which may become due for this application under 37 C.F.R. §1.17 by check, the Commissioner is hereby authorized to charge such fee(s), and any additional fees which may be required in this application under 37 C.F.R. §§1.16-1.17 during its entire pendency, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

Fitch, Even, Tabin & Flannery



Kendrew H. Colton, Reg. No. 30,368

Samuel P. Burkholder, Reg. No. 40,541

Date: November 22, 2005

*OFFICIAL CORRESPONDENCE TO*

*Customer No. 42798*

FITCH, EVEN, TABIN & FLANNERY  
1801 K Street, NW, Suite 401L  
Washington, DC 20006  
Tel: (202) 419-7000, Fax: (202) 419-7007

10/557611

MAP20 Rec'd PCT/PTO 22 NOV 2005

APPLICATION UNDER UNITED STATES PATENT LAWS

Atty. Dkt. No. 7388/84495

Invention: TRANSDERMAL FORMULATION FOR EXTERNAL APPLICATION  
CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY  
ANALGESIC, AND INTERLEUKIN-1 $\alpha$  PRODUCTION INHIBITOR

Inventor(s): Atsutoshi IKESUE  
Kazuhisa YOSHITAKE  
Kenji ATARASHI  
Koichi IKESUE  
Michinori SAKAI  
Amarender REDDY  
Yoshiteru MOTOKI  
Dange VEERAPANENI

CUSTOMER NO. 42798

Fitch, Even, Tabin & Flannery  
1801 K Street, N.W. - Suite 401L  
Washington, D.C. 20006-1201  
Telephone: (202) 419-7000

This is a:

- PCT National Phase Application
- The complete disclosure of  
PCT/JP2004/007403, filed May 24,  
2004 is incorporated by reference.

SPECIFICATION